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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/618,223

07/11/2003

Eric K. Mangiardi

000100.0015

4411

37305 7590 10/14/2008

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EXAMINER

LLOYD, EMILY M

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

10/14/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/618,223

**Applicant(s)**

MANGIARDI ET AL.

**Examiner**

EMILY M. LLOYD

**Art Unit**

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-24,37,39-42,45,46,48-50,52-54,56 and 57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-24,37,39-42,45,46,48-50,52-54,56 and 57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This office action is in response to Applicant's 27 March 2008 amendment. The Examiner acknowledges the amendments to claims 1, 7, 24, 37, 46, 49 and 47, and the cancellation of claims 44, 47, 51 and 55. Currently, claims 1, 3-8, 10-24, 37, 39-42, 45, 46, 48-50, 52-54, 56 and 57 are pending.

#### ***Claim Rejections - 35 USC § 112***

2. Claims 5, 12 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claims 1, 7 and 37 recite that the inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit. Claims 5, 12 and 41 recite that the distal ends of the legs are coupled together as shown in the embodiment of figures 14-18. The original disclosure states, "when the legs are constrained by the exterior conduit 130 they lay substantially flush with respect to one another" (page 9, lines 16-17). However, this statement pertains to the embodiment of figures 1-13 when the distal ends of the legs are not coupled together. Regarding the embodiment of figures 14-18, the original disclosure states, "when the measurement assembly is retracted, the legs are relaxed and reside adjacent one another so that the legs may be retracted within the exterior conduit" (page 10, lines 23-26). However, the original disclosure does not appear to

support inward facing surfaces of the legs in the embodiment of figures 14-18 being in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit.

Therefore, the subject matter of claims 5, 12 and 41 does not appear to be properly supported by the original disclosure.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3-8, 10-24, 37, 39-42, 45, 48, 52 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain (US 5,919,147) in view of Colvin et al. (US 5,010,892), Haddock et al. (US 6,712,771), Doi (US 6,033,359), and Baxter-Jones (US 6,450,977).

Jain teaches a body lumen measuring device for measuring a target segment of a lumen of a patient so as to select a suitable interventional prosthesis. The device (10) includes an exterior conduit (22); an interior conduit (24) slidably disposed within the exterior conduit and having a depth marking mechanism (42); a measurement assembly (26 or 54) including a plurality of legs (44 or 56, 58) coupled with each other proximal the distal ends thereof and coupled about the distal end of the interior conduit; and a handle (24, 30) operatively connected with the measurement assembly. The handle includes means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration. The inward facing surfaces along a portion of the legs are in flush contact with one another along a portion distal of the proximal ends when the measurement assembly is closed within the exterior conduit (see figure 2). The legs form an acute angle with respect to one another as the measurement assembly is moved distally in relation to the first conduit (see figures 3 and 6). In an alternative embodiment, the distal ends of the legs are coupled together (see figures 5 and 6). The handle further includes the measurement indicator, wherein target lumen dimensions are calculated

based on the relative distance the handle travels along the continuum between the first and second handle locations (column 1, lines 45-47). The device is used to measure a target segment of a lumen of a patient so as to select a suitable interventional prosthesis (column 1, lines 16-20). In operation, the device is introduced into an appropriate anatomical orifice of a patient; delivered adjacent a target segment of a lumen within the patient; and the diameter of the target segment is measured within the patient (paragraph bridging columns 3 and 4). The device further comprises an optical scope to view placement of the measurement assembly (column 3, lines 57-58).

Jain teaches all of the limitations of the claims except that the exterior conduit has measurement markers formed on a portion thereof, that the depth markings on the interior conduit are visible through the exterior conduit, measuring length of a target segment, measuring dimensions of a stenotic segment, that the inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit, that the lumen facing surface of each of the legs includes a plurality of measurement markers, and that the exterior conduit is configured to engage the measurement markers.

Colvin et al. teach a body lumen measuring device that is capable of allowing a user to calculate the length and diameter of a suitable interventional prosthesis as well as the height and length of stenosis during the same exploratory procedure. The device (10) includes an exterior conduit (12) having measurement markers (24) formed on a portion thereof; an interior conduit (16) slidably disposed within the exterior conduit and

having a depth marking mechanism (22) which may be visible through a portion of the exterior conduit (20); a measurement assembly including a plurality of legs (54a-54c) coupled with each other proximal the distal ends thereof and coupled about the distal end of the interior conduit; and a handle (14) operatively connected with the measurement assembly. The handle includes means for opening and closing the measurement assembly (18) by actuating the handle along a continuum between a first closed configuration and a second open configuration. An optical endoscope may be operatively coupled therewith, so that the measuring step may be accomplished using the optical endoscope. The device may be used to measure the diameter and length of a target segment of the lumen within the patient, including the height and length of the stenosis (column 3, lines 65-66).

Applicant has not disclosed that using a measurement indicator arrangement having a plurality of measurement markers formed on a portion of the exterior conduit and a depth marking mechanism on the interior conduit that is visible through a portion of the exterior conduit solves any stated problem or is for any particular purpose. Moreover, it appears that the measurement indicator arrangement of Jain, or applicant's invention, would perform equally well with the plurality of measurement markers formed on a portion of the exterior conduit and a depth marking mechanism on the interior conduit that is visible through a portion of the exterior conduit, similar to the arrangement taught by Colvin et al. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Jain to include a measurement indicator arrangement similar to that of Colvin

et al., because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Jain.

As noted above, Colvin et al. teach measuring height and length of body lumens including that of stenotic lumens to facilitate accurate sizing of a device to be placed in the lumen. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have measured the length of a target lumen and height and length of stenoses as taught by Colvin et al. in the method of Jain in order to obtain additional information about the proper size of a device to be inserted into a body lumen.

Haddock et al. disclose legs (302 in figures 3A-B or 310 in figure 3C) of a measurement assembly, wherein inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within an exterior conduit (300). The flush legs of Haddock et al. would be advantageous since relative movement of the legs would be prevented when the legs are stored within the exterior conduit. Thus, potential damage to the legs would be avoided before the device is used. Furthermore, one of ordinary skill in the art would recognize that allowing the legs to be closed in flush contact along their entire lengths would allow the diameter of the conduit to be reduced allowing access to smaller lumens in the body. It would have been obvious to one having ordinary skill in the art at the time of invention to have modified the legs of Jain as modified by Colvin et al. so that the legs are in flush contact along their entire lengths when the measurement assembly is closed within an exterior conduit as taught by



Haddock et al. in order to prevent relative movement and damage to the legs before the legs are extended from the exterior conduit and to reduce the overall diameter of the conduit so that smaller body lumens can be accessed by the device.

Doi teaches a plurality of measurement markers (8) on the lumen facing surfaces of legs (3) that are capable of providing information regarding the diameter of the target segment using an optical system (column 3, lines 48-52). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have made a plurality of measurements markers on each leg of Jain as modified by Colvin et al. and Haddock et al. as taught by Doi in order to achieve the predictable result of providing appropriate markers on a measurement tool to obtain measurements within a patient.

Baxter-Jones teaches a lip that extends from the distal end of an exterior conduit (1116) to engage detents (1130) defined in an elongated measurement member (1108). Since the exterior conduit (1116) is flexible, the exterior conduit will temporarily form a lip when slid over the detents. Baxter Jones teaches incorporating the detents with measurement markings for the purpose of locking the elongated measurement member (1108) with the exterior conduit (1116).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a lip that engages detents as taught by Baxter-Jones in the device of Jain as modified by Colvin et al., Haddock et al. and Doi in order to achieve the predictable result of releasably locking the legs with the exterior conduit.

7. Claims 46, 49, 50, 53, 54 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain as combined with Colvin et al., Haddock et al., Doi, and Baxter-Jones as applied to claims 1, 3-8, 10-24, 37, 39-42, 45, 48, 52 and 56 above, and further in view of Baumann (US 4972584).

Jain as combined with Colvin et al., Haddock et al., Doi, and Baxter-Jones teach the devices of claims 45 and 56 and the methods of claims 48 and 52. Jain as combined with Colvin et al., Haddock et al., Doi, and Baxter-Jones do not teach that the distal end of the exterior conduit comprises a lip protruding from the inner surface that is configured to engage the detents. Baumann teaches an exterior conduit (54) comprising inner and outer surfaces, and wherein the distal end of the exterior conduit comprises a lip (46 in Figure 3 or 57 in Figure 6 or 7) protruding from the inner surface that is configured to engage detents (49), and measuring by displacing the exterior conduit and measurement assembly (49a on 11) relative to one another such that the lip engages a detent (Figure 6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the lip protruding from the inner surface that is configured to engage the detents as taught by Baumann in the invention of Jain as modified by Colvin et al., Haddock et al., Doi, and Baxter-Jones to provide for easily repeatable measurements among various users, without the need for estimating how far between two detents or measurements the device is. As combined with Jain as modified by Colvin et al., Haddock et al., Doi, and Baxter-Jones, the lip would engage the detents defined in the legs.

***Response to Arguments***

8. In regards to the 35 U.S.C. 112 first paragraph rejection of claims 5, 12 and 41, Applicant argues that the term adjacent was used to describe legs that are flush to one another. However, stating that the legs are adjacent does not necessarily mean that the legs are in flush contact along the entire length as claimed. Applicant further argues that the only difference between the embodiments is that the distal ends of the legs are coupled together in figures 14-18. However, since different language was used in the original disclosure to describe the configuration of the legs in the closed configuration for each embodiment, one can not presume that the flush contact in the first embodiment is implied in the second embodiment. In regards to the comments regarding Figure 18, it is respectfully submitted that one would need to see a cross-sectional view of the second embodiment in the closed configuration to determine if the legs are in flush contact.

9. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Specifically, Baxter-Jones teaches an exterior conduit that engages detents that coincide with measurement markings for the purpose of measuring the body. Claimed elements not taught by Baxter-Jones are provided in the other references discussed above. Additionally, the measurement indicators on the lumen facing surfaces was combined with the legs of Jain and Colvin et al., and as combined, the legs of Jain and

Colvin et al. with measurement indicators (Doi) and detents (Baxter-Jones) would work with the indicator of Baxter-Jones.

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LLOYD whose telephone number is (571)272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd  
Examiner  
Art Unit 3736

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